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June 12, 2015

Stephanie Vaughn  
17-mile LPRSA RI/FS Remedial Project Manager  
U.S. Environmental Protection Agency, Region 2  
290 Broadway  
New York, NY 10007-1866

***Via Electronic Delivery***

**Re: Lower Passaic River Study Area (LPRSA) Draft Baseline Ecological Risk Assessment (BERA)  
– USEPA Region 2 Comments – May 2007 Administrative Agreement and Order on  
Consent for Remedial Investigation/Feasibility Study – CERCLA Docket No. 02-2007-2009  
(AOC)**

Dear Ms. Vaughn:

This letter is in further follow up to USEPA Region 2 (Region 2) comments sent to the Cooperating Parties Group (CPG) on May 1, 2015 with respect to the draft 17-mile BERA submitted to Region 2 on June 13, 2014. Specifically this letter addresses Region 2's directive to resubmit the BERA within 60 days (i.e., June 29, 2015) of the CPG's receipt of the May 1 EPA Comments. For the reasons discussed herein, it is simply not tenable to comply with this directive. Further, the CPG provides schedule milestones which were discussed during the June 1, 2015 Region 2-CPG teleconference.

**Region 2's May 1, 2015 comments are incomplete and are missing critical information required to revise the 17-mile BERA.**

Region 2's General Comment 6 (Reference and Background) and Specific Comment 71 (Sediment Quality Triad) remain incomplete and refer to information or materials that the Region has repeatedly promised to provide to the CPG since May 1, but has not yet done so. Therefore, the BERA comments remain incomplete and prevent the CPG from providing a prompt and timely revision to the BERA.

With regard to reference and background, it is very troubling that the Region was meeting with the Partner Agencies during the week of June 1, 2015 to discuss the process of developing reference and background data sets. It is inconceivable that nearly one year after the submission of the 17-mile BERA and over a month after the Region provided its BERA comments, Region 2 still has not made a decision on this critical issue and provided the necessary information to the CPG. The failure of Region 2 to come to closure on a process to develop background and reference data sets for the 17-mile LPRSA in a timely and consistent manner has materially and adversely impacted the RI/FS process.

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Delay and indecision have characterized the Region's resolution of this matter<sup>1</sup>. Discussion on reference and background for the 17-mile RI/FS began nearly 8 years ago during a Region 2 and CPG Meeting on September 6, 2007. Region 2 provided the June 2013 "Passaic River RARC Reference and Background Definitions and Usage Document," which the CPG used in its development of reference and background. During the May 29, 2014 Region 2-CPG teleconference, the Region 2 representatives instructed the CPG to submit the draft 17-mile BERA using the CPG's approach to reference and background conditions as discussed with the Region over the previous two years.

In addition, Region 2 demanded in its April 29 and May 14, 2014 letters that the CPG immediately submit the 17-mile Baseline Human Health Risk Assessment (BHHRA) and the 17-mile BERA, which the CPG delivered on June 6 and 13, 2014, respectively. As a result, the CPG and its consultants employed a scientifically-sound approach, consistent with previous discussions with Region 2 and USEPA guidance, to develop CERCLA reference and background conditions for the entire 17-mile LPRSA, which only now Region 2 severely criticizes, but without providing any alternative resolution. LPRSA reference and background conditions should be based solely on USEPA guidance and the Region's 2013 definitions (cited above).

#### **17-mile BERA Response Milestones**

The CPG has conducted discussions with Region 2 regarding its preliminary concerns related to the BERA comments during telephone conferences on May 7, 14, 21 and June 1, 2015. The CPG also submitted letters to Region 2 on May 15 and May 29, 2015 that the Region has yet to respond to. Specifically, those letters are:

- CPG's May 15 letter which identified a number of comments that are inconsistent with the Region's prior approvals and/or comments provided on earlier documents (attached).
- CPG's May 29 letter, which documented the Group's understanding of the agreed resolution for four comments related to data use in the BERA and BHHRA (attached).

As a result of the above, and as discussed during the June 1, 2015 Region 2-CPG teleconference, the CPG will respond to the Region's BERA comments using the following schedule milestones:

- As discussed and offered by Region 2 during our June 1 teleconference, and pursuant to my June 5 e-mail to you, the CPG would like to receive only Region 2's process and/or comments on establishing the LPRSA reference and background condition and not the data set(s) that would be generated by it;

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<sup>1</sup> Section 2 of Appendix B of the draft October 2013 Risk Assessment and Risk Characterization plan provides a summary of the discussions between Region 2 and the CPG during the period from 2011 to 2013.

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- The CPG will begin the process of revising those portions of the BERA that are resolved as a result of the CPG's May 15 and May 29 letters;
- CPG will draft a response to comments (RTCs) as directed by Region 2; this document will not be completed until after the receipt of information from Region 2 related to Comments 6 and 71, as well as any other supplemental information related to its BERA comments that the Region provides;
- The CPG will evaluate these supplemental materials and provide a proposed date to deliver the RTC's for the Region's review;
- The CPG requests that Region 2 provide a proposed date to respond to and/or discuss the CPG's RTCs; and,
- Once Region 2 and the CPG reach a resolution on the BERA RTCs, the CPG will provide a proposed date for delivering a revised 17-mile BERA.

The CPG continues to reserve its right to take other steps, such as invoking dispute resolution under Section XV of the LPRSA AOC, to protect its interests, after Region 2 provides all of its comments on the 17-mile BERA, its responses to CPG's May 15 and May 29 letters, its response to this letter, and its responses to the CPG's BERA RTCs.

The CPG requests that Region 2 include this letter into the Administrative Record for the 17-mile LPRSA operable unit of the Diamond Alkali Superfund Site.

Please contact Bill Potter or me with any questions or comments.

Very truly yours,  
**de maximis, inc.**



Robert H. Law, PhD  
CPG Project Coordinator

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**Attachments**



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May 15, 2015

Stephanie Vaughn  
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***Via Electronic Delivery***

**Re: Lower Passaic River Study Area (LPRSA) Draft Baseline Ecological Risk Assessment (BERA)  
– USEPA Region 2 Comments – May 2007 Administrative Agreement and Order on  
Consent for Remedial Investigation/Feasibility Study – CERCLA Docket No. 02-2007-2009  
(AOC)**

Dear Ms. Vaughn:

This will acknowledge and respond to, on a strictly preliminary basis, the USEPA Region 2 (Region 2) comments sent to the Cooperating Parties Group (CPG) on May 1, 2015 (one day after the CPG submitted the draft 17-mile LPRSA Feasibility Study to Region 2), with respect to the draft BERA the CPG submitted to Region 2 on June 13, 2014. The CPG believes the draft BERA should have been accepted by Region 2, pursuant to paragraph 44 (a or b) of the AOC. The CPG is continuing to evaluate the extensive list of comments Region 2 provided and reserves its right to respond in detail in due course.

A primary concern of the CPG with Region 2's BERA comments is the fact that they appear to ignore the agreements and understandings reached by Region 2 and the CPG through the extensive amount of interactions (i.e., meetings, calls, correspondence), as well as the preparation and review of risk assessment documents, throughout the RI/FS process since 2007. The following examples highlight major problems with the comments:

- General Comment 2, which directs the CPG to treat ecological exposure areas using an approach that is inconsistent with the ecological risk assessment presented in Region 2's 8-Mile FFS RI (see Appendix D, Section 4.2.1 paragraph 1).
- General Comment 3 relates to the incorporation of the common carp (an invasive species introduced to the Lower Passaic River) into the 17-mile BERA.
- General Comment 6 and Specific Comment 71 are explicitly incomplete and refer to information or materials Region 2 will provide to the CPG, but has not yet done so, leaving the CPG in a position of being directed to prepare expensive and time consuming responses and revisions without knowing what revisions are required or will be acceptable;
- Numerous comments that are inconsistent with Region 2's approved August 2009 Problem Formulation Document (PFD), the October 2013 Draft Risk Assessment and Risk Characteristic plan (RARC), Region 2's previous RARC comments and the April 2014 Data

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Usability Memorandum (and associated comments). Some specific examples identified thus far include:

- General Comment 11 - criticizes the approach for dealing with non-detect (ND) values and states that the same approach should be used in both the BERA and Human Health Risk Assessment (HHRA). The CPG used NDs values consistent with the April 2014 Data Usability Memorandum, which addressed the Region's 2010 comments on an earlier version of this memorandum. The CPG did treat ND values the same in the BERA and HHRA.
- General Comment 13 - states that evaluation of polycyclic aromatic hydrocarbons (PAHs) in sediment should be conducted using 34 PAHs. The CPG used 16 PAHs which is consistent with the April 2014 Data Usability Memorandum and the Region's 2010 comments. Based on the EPA-CPG discussions on May 7 and 14, this comment may be resolved.
- Specific Comment 44 - requests that risk questions cited from the final PFD be reworded. However, this would make the risk questions in the BERA different than the risk questions in the Region 2-approved PFD.
- Specific Comment 64 directs that *"all of the toxicity data should also be compared to the control data as per previous agreement with EPA"*. The CPG has presented a comparison of the toxicity data to the control data in the Fall 2009 Sediment Toxicity Test Data Report for the Lower Passaic River Study Area, Draft, January 31, 2012. The October 2013 RARC calls for a comparison to reference data as part of the risk characterization in the BERA. Moreover, EPA's January 2013 Revised Comments on the NBSA Problem Formulation Document (dated December 2012) states: *"use of control sediment is for QA/QC purposes; not for making site-related decisions. Ecological risk decisions should be based on responses relative to reference and concentration-response relationships."*
- Specific Comment 78 - requires evaluation of all surface water samples for the benthos assessment, not just bottom samples. However, this contradicts Region 2's September 2010 RARC comments which stated that benthos should be evaluated with surface water *"immediately above the sediment, from 0-6 inches."*
- Specific Comments 153 and 155 (and other SLERA-related comments) - require the CPG to change from the endpoint and receptor approach presented in the endpoint assessment table in the Region 2-approved PFD.
- Specific Comment 172 - states that the COPEC screening process described in the SLERA and summarized in three flow charts is inappropriate and that numerous revisions are necessary. The CPG addressed Region 2's November 2010 comments on these flow charts in its October 2013 revised draft RARC. Region 2 did not provide any additional comments on these flow charts in its January 2014 comments.

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- Specific Comment 219 - requests a summary of biomass data that the CPG never collected and does not exist. Other comments indicate a lack of LPRSA project understanding and history by some reviewers.

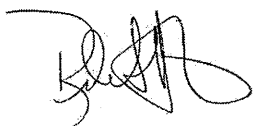
Of note, EPA stated in its May 14, 2014 letter to the CPG that “.... EPA has not directed the CPG to deviate from the 2009 Problem Formulation Document.” The Region's BERA comments now appear to be deviating from the 2009 PFD that it approved.

The CPG has already begun discussions with Region 2 with telephone conferences on May 7 and 14, and expects to continue these discussions on a weekly basis first on the BERA comments and then on anticipated Baseline Human Health Risk Assessment comments. The CPG will continue to identify and elaborate its concerns as was done on the two recent telephone conferences and as expressed above in an attempt to resolve the issues expeditiously and informally. As is clear, Region 2 has indicated that the comments it has provided are not complete. Thus, the CPG reserves its right to take other steps, such as invoking dispute resolution under Section XV of the AOC to protect its interests, after Region 2 provides all of its comments on the BERA. However, to the extent that Region 2 deems its comments complete and not preliminary, then this letter constitutes the invocation of dispute resolution regarding the same pursuant to Section XV of the AOC.

The CPG requests that Region 2 include this letter into the Administrative Record for the 17-mile LPRSA operable unit of the Diamond Alkali Superfund Site.

Please contact Bill Potter or me with any questions or comments.

Very truly yours,  
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May 29, 2015

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**Via Electronic Delivery**

**Re: Lower Passaic River Study Area (LPRSA) Draft Baseline Ecological Risk Assessment (BERA)  
– USEPA Region 2 May 1, 2015 Comments – Data Use Comment Resolution**

Dear Ms. Vaughn:

This letter was prepared in response to discussions between USEPA Region 2 (Region 2) and the Cooperating Parties Group (CPG) regarding resolution of specific data use comments provided by Region 2 in its May 1, 2015 comments on the CPG's draft BERA dated June 13, 2014. Specifically, during the May 7, 14, and 21, 2015 EPA-CPG teleconferences, comments 11, 13a, 13b, 51, and 52 were raised by the CPG, because these comments were inconsistent with previous agreements, documents and/or direction from Region 2. In response, Region 2 requested during the May 21 teleconference that the CPG submit a letter documenting the resolution and resolution language (if applicable) for each of the comments. The following describes the comment and the resolution reached between Region 2 and the CPG on these comments.

**Region 2 Comment 11** – “Setting non-detect values to zero rather than using EPA-approved statistical software (e.g., ProUCL) requires justification beyond just a discussion in the uncertainty sections. It is unclear why a standardized approach is not used throughout the draft BERA. Setting non-detect values to zero may underestimate risks where reporting limits are high. The same approach for addressing non-detect values should be used in both the BERA and the HHRA.”

**CPG Response to Comment 11** - The treatment of non-detects (NDs) in the BERA and the Baseline Human Health Risk Assessment (BHHRA) followed the rules described in Sections 4.1 and 5.3 of the Data Usability and Data Evaluation Plan (Data Usability Plan; Windward and AECOM in prep). The Data Usability Plan has been reviewed and commented on by Region 2 multiple times. The most recent version of the Data Usability Plan was submitted to Region 2 on May 15, 2014, and addressed the presumed final two comments provided by Region 2 on April 10, 2014<sup>1</sup>.

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<sup>1</sup> The Data Usability and Data Evaluation Plan was submitted to Region 2 on February 26, 2010, a revised draft was submitted on April 13, 2012, and a final revised draft on May 15, 2014. Region 2 commented on the 2010 and 2012 drafts; comments were received on April 1, 2010 and April 10, 2014, respectively. Region 2 has not provided final approval or additional comments on the CPG's May 15, 2014 draft document.

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Applicable sections of the Data Usability Plan and BERA are included as an attachment to this letter.

Consistent with Section 5.3 of the Data Usability Plan, the ProUCL recommended detection limit substitution method was used in generating upper confidence limits (UCLs) for both baseline risk assessments. Section 4.3.7 of the BERA states:

*"Because ProUCL has an option for handling non-detect data (USEPA 2013b), all data (detected and non-detected) were used."*

Section 4.4.1 of the BHHRA states:

*"Reporting limits for non-detected data were entered into ProUCL at the full reporting limit. ProUCL identifies the appropriate method with which to estimate the concentrations of the undetected data rather than simply substituting a value such as the detection limit or one-half the detection limit."*

Consistent with Section 4.1 of the Data Usability Plan, for COPCs where sums are used (e.g., Total PCBs, Dioxin TEQs), the sum is calculated as the sum of the detected congeners. If none of the individual congeners were detected, the total concentration was flagged as non-detected (U qualified) with a reporting limit equal to the maximum reporting limit of the individual congeners. The maximum reporting limit was then included in the derivation of the UCL for the total in ProUCL, and ProUCL determined the appropriate detection limit substitution method.

A discussion of the impacts to exposure concentrations and risk estimates based on treatment of NDs in sums (as zero (i.e., the sum of detects only), one-half of the detection limit (DL), and full DLs) is included in the uncertainty sections of both the BERA (Section's 6.5.4.2, 7.1.4.2, 7.3.4.2, 7.4.4.2, 8.1.4.2, 8.2.4.2, 9.1.4.2) and the BHHRA (Section 7.2.2.4). This approach is entirely consistent with Region 2's comment on this matter. As stated in Region 2's Data Usability Memo comments received on April 1, 2010:

*"EPA is still evaluating how best to handle non-detects for congeners with multiple congeners, and Region 2 has contacted Headquarters for further guidance. As such, additional comments on this section will be made at a later date. In the meantime, however, it may be useful to select some examples from the existing dataset to determine the overall impact of using zero, one-half the detection limit, or the full detection limit on the calculated concentrations." [emphasis added]*

The analyses in both the BERA and the BHHRA demonstrate and document that the impact of alternate methods of treatment of NDs in sums would have a negligible impact on risk estimates. Furthermore, the approach taken in the BERA and BHHRA is fully consistent with the 17-mile LPRSA project-specific plans, USEPA guidance, and other sites.

**Resolution to Comment 11** - Region 2 asked the CPG to provide text documenting where this information on the treatment of NDs and the evaluations are located in the BERA submitted on



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June 13, 2014 and the BHHRA submitted on June 6, 2014. The Data Evaluation and Reduction section (Section 4.3 Data Reduction Rules) of the BERA describes how NDs are treated. In addition, each BERA uncertainty section (uncertainties in risk characterization) discusses the treatment of NDs:

- Benthic Assessment (Section 6; specifically Section 6.5.4.2) – Table 6-30 has an evaluation of treatment of NDs for surface water for invertebrates.
- Fish Assessment (Section 7; specifically Sections 7.1.4.2, 7.3.4.2, and 7.4.4.2) – Table 7-10 has an evaluation of the treatment of NDs for fish tissue. Table 7-26 has an evaluation of the treatment of NDs for surface water for fish. Table 7-30 has an evaluation of the treatment of NDs for fish eggs.
- Bird Assessment (Section 8; specifically Sections 8.1.4.2 and 8.2.4.2) – Table 8-13 has an assessment of the treatment of NDs for bird diet. Table 8-21 has an assessment of the treatment of NDs for the bird egg evaluation.
- Mammal Assessment (Section 9; specifically Section 9.1.4.2) – Table 9-15 has an evaluation of the treatment of NDs for mammalian diet.

Similar sections are provided in the BHHRA:

- Section 3.2.1 (Summary Statistics) describes how total PCBs and dioxin toxic equivalence concentrations were calculated by summing detected congeners.
- Section 4.4.1 (Calculation of Exposure Point Concentrations) describes how full reporting limits were entered into ProUCL, and that ProUCL then identified the appropriate method for estimating concentrations of non-detects.
- Section 7.2.2.4 (Approach for Handling Non-Detect Results in Totals) discusses uncertainties associated with summing only detected congeners for totals and provides comparisons based on using one-half of the reporting limit and the full reporting limit in sums. Table 7-2 presents a comparison of calculated sums for TCDD-TEQ, PCB-TEQ, and total PCBs using three ND treatments (ND = 0, ND=1/2 RL, and ND=RL) for fish and crab tissue types.
- Section 7.2.2.4 also presents an evaluation of the impact of using USEPA's Advanced KM TEQ Calculator (provided in EPA's Dioxin Tool Box) on the maximum and mean TCDD-TEQs in sediment, surface water, and tissue. The KM TEQ Calculator provides an alternate method of estimating non-detect congeners based on the Helsel's 2010 work.

No changes will be made in the handling of NDs in the BERA and the BHHRA.

**Region 2 Comment 13a** – *"The total TEQs should be evaluated by a calculation of the sum of PCDD/PCDF/PCB TEQs together for each individual sample."*

**CPG Response to 13a** – The CPG notes that these sums were provided in the June 13, 2014 BERA. Section 4 of the BERA, Data Evaluation and Reduction, describes the process for calculating Total TEQs, which are the sum of all TEF-weighted PCDD/PCDF congeners and dioxin-like PCB

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congeners on a sample basis, consistent with the methods presented in Table 4-1 and Section 4.1 of the Data Usability Plan. Moreover, the TEQ summation approach used in the BERA is consistent with EPA's 2013 guidance, *Use of Dioxin TEFs in Calculating Dioxin TEQs at CERCLA and RCRA Sites*.

**Resolution to Comment 13a** – During the May 21 call, Region 2 stated that this was a simple misunderstanding and this issue could be resolved by adding the sums to tables (in addition to the individual constituents). The CPG agreed to present the totals at the bottom of the tables where applicable (e.g., tables of COIs and COPECs in the SLERA).

**Region 2 Comment 13b** - *"In addition, evaluation of PAHs in sediment should be conducted using EPA's toxic unit approach, calculated for 34 PAHs".*

**CPG Response to Comment 13b** - The operational definition and summing methods for PAHs (as low molecular weight PAHs, high molecular weight PAHs, and total PAHs [as the sum of 16 PAH compounds]) were presented in Section 4.1 of the Data Usability Plan. The only comment regarding PAH sums was provided by Region 2 in their April 1, 2010 comments on the February 26, 2010 draft Data Usability Plan:

*"The rationale for inclusion of an alkylated PAH (2-methylnaphthalene) in the PAH totals should be included."*

In response to this comment, CPG removed 2-methylnaphthalene from the PAH sum in the revised draft Plan dated April 13, 2012, and EPA did not comment on PAH sums in their April 10, 2014 comments on the revised draft Data Usability Plan. Further, the PAH sums presented in all of the data summary reports submitted by CPG to Region 2 were calculated using the method presented in Section 4.1 of the Data Usability Plan. Moreover, Region 2 provided no comments regarding the summing of PAHs in these data summary reports:

- 2009 Fish and blue crab tissue chemistry data for the Lower Passaic River Study Area (last submitted September 19, 2011; Windward 2011);
- 2010 Small forage fish tissue chemistry data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012a);
- 2009 and 2010 Sediment chemistry data for the Lower Passaic River Study Area (last submitted May 23, 2014; Windward 2014c); and
- 2011 Caged bivalve study data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012b).

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**Resolution to Comment 13b** – Region 2 stated during the May 21 teleconference that this issue has been resolved. The CPG should only evaluate the 16 PAHs agreed to previously. Region 2 asked the CPG to qualitatively discuss 34 PAHs in the uncertainty section of the BERA.

**Region 2 Comment 51** – *"A set of rules should not be used to determine what value to use when multiple values are available. Instead of a set of rules, each value that has multiple results should be evaluated and the most appropriate value should be used. High-resolution methods are not superior to the low resolution method. A table listing the samples with their multiple results, along with a column for rationale of which value is chosen should be included."*

**CPG Response to Comment 51** - This comment is contrary to the design and intent of the Data Usability Plan that CPG and EPA developed with the express intent of establishing a standard and consistent set of rules to be applied in both baseline risk assessments. The rules for selecting a single value when multiple values are reported are presented in Section 4.2 of the Data Usability Plan as well as the data summary reports submitted to Region 2 (see above list in CPG Response Comment 13b) since 2011, all of which went through multiple rounds of Region 2 comments. Specifically, Section 4.2.1 of the Data Usability Plan discusses the selection of a single result when multiple values are available due to analyte overlap. Region 2 provided no comments regarding data rules for selecting single values when multiple results were reported in either the drafts of the Data Usability Plan or any of the subsequent data summary reports listed above in response to Comment 13a.

**Resolution to Comment 51** – Region 2 stated that the CPG should follow the rules as outlined in the Data Usability Plan in both the BERA and the BHHRA, and as previously submitted in the data summary reports.

**Region 2 Comment 52** – *"The rules provided for evaluating the field duplicates and laboratory replicates are generally acceptable; however, for values that fall under the first bulleted rule, a table should be created that shows both values to confirm that the results are not vastly different. If the values are vastly different, then additional text should be provided to explain why averaging the results is valid."*

**CPG Response to Comment 52** - The rules for evaluating field duplicates and lab replicates were presented the Data Usability Plan and a number of data summary reports, all of which went through multiple rounds of Region 2 review and comment.

In addition to the impracticality of this comment (i.e., the level of detail for data documentation sought by Region 2 would be significant in both the BERA and BHHRA), this comment directs the CPG to take an approach inconsistent with previous agreements and plans. No comments were provided by EPA regarding treatment of field and laboratory replicates presented in Section 4.2.2 of the Data Usability Plan. Further, the same treatment of

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laboratory replicates has been applied in the data summary reports prepared by the CPG and submitted to EPA since 2011. It should be noted that the data summary reports submitted by CPG to EPA (listed above in response to comment 13a) present all reported field duplicate results (i.e., sediment field duplicates). In addition, Appendix A of the BHHRA presents all of the analytical data used, including individual results for parent and duplicate samples.

**Resolution to Comment 52** – Region 2 stated that the CPG should follow the rules as outlined in the Data Usability Plan in both the BERA and the BHHRA, and as previously submitted in the data summary reports.

The CPG requests the Region to confirm its agreement with the resolution of these comments. The CPG urges the Region to review its 17-mile BHHRA comments currently in preparation and address and revise similar comments.

The CPG requests that Region 2 incorporate this letter and its attachments into the Administrative Record for the 17-mile LPRSA operable unit of the Diamond Alkali Superfund Site.

Please contact Bill Potter or me with any questions or comments.

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CPG Project Coordinator

cc: Ray Basso, EPA Region 2  
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Willard Potter, CPG Project Coordinator

Attachments